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09/674,597	04/09/2001	Zheng Xin Dong	00537-169002	1308

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EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,597

Applicant(s)

DONG ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 8, 16-22 and 30-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 9-15 and 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/13/04</u> | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

Status of Application, Amendments, and/or Claims

The Amendment and Information Disclosure Statement, sent 13 October 2004, have been entered into the record.

Claims 1-3, 7, 9-15 and 23-29 are under examination in the Instant Application.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

Withdrawn Objections And/or Rejections

Continuity

The objection to the Specification, because it had not complied with one or more conditions for receiving the benefit of an earlier filing date, is *withdrawn*. Applicants amended the Specification to insert references to parent applications (15 November 2004).

Brief description

The objection to the Specification for purportedly lacking a Brief Description of the Several Views of the Drawings, is *withdrawn*. Applicants pointed out that there are no drawings in the instant Specification and thus, according to MPEP § 608.01(f), no Brief Description is required.

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Sequence Rules

The objection to the instant Application for not complying with the sequence rules is *withdrawn*. Applicants amended the Specification to insert SEQ ID NO's where appropriate (15 November 2004).

Claim Rejections - 35 USC § 112, first paragraph - enablement.

The rejection of Claims 1-3, 7, 9-15 and 23-29 under 35 U.S.C. 112, first paragraph, for lack of enablement, is withdrawn based on Applicant's arguments (15 November 2004).

Maintained/New Objections and/or Rejections

Claim Objections

Claim 1-3, 7, 9-15 and 23-29 are objected to for reciting or encompassing non-elected inventions (for example, peptides other than SEQ ID NO: 16).

The amendment filed 15 November 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The descriptor "human" added to describe the claimed PTH analogue is not found in the Specification as filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections- 35 USC § 112, first paragraph – Written Description

Claims 1-3, 7, 9-15 and 23-29 are rejected under 35 U.S.C. 112, first paragraph, for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons for this rejection under 35 U.S.C. § 112 are set forth at pp. 5-7 of the previous Office Action (14 May 2004).

Claims 1-3, 7, 9-15 and 23-29 are directed to PTH analogues, truncated analogues and compositions of PTH analogues. Dependent claims recite short peptides in which almost every residue may be substituted from a large set of amino acids, or even deleted (Claims 7, 9-15 and 23-29).

The specification teaches several specified polypeptides (for example: SEQ ID NO: 16). However, the specification does not teach functional or structural characteristics of all compounds and all polypeptides encompassed by the claims (i.e., that bind selectively to the human PTH2 receptor). The description of one polypeptide PTH analogue (SEQ ID NO: 16) is not adequate written description of an entire genus of functionally equivalent polypeptides and compounds.

Applicants discuss the legal standards applied when evaluating Written Description, stating that "[t]he description requirement is simply that the claimed subject matter must be described in the specification... [i]t is not necessary that the application describe the claim

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limitations exactly, but only so clearly that persons of ordinary skill in the art would recognize from the disclosure that applicant's invention included those limitations" (page 28, 15 November 2004), and cite case law as support (*In re Smythe*, 1973, 480 F. 2d 1376, 178 USPQ 179 and *In re Moore*, 1971, 439 F.2d 1232, 169 USPQ 236).

Applicants' arguments have been considered but are not deemed persuasive. The examiner takes no issue with the discussion of general requirements for evaluating Written Description in this case. However, the case law cited does not support the Applicant's position that it is not necessary that the application describe the claim limitations precisely. In *In re Smythe*, for example, it was determined that *literal definitions* of chemical species are indeed required. In some cases, more often outside of the fields of chemistry and biology, a subject matter does not need to be described literally, with the test being whether one skilled in the art would understand that the subject matter claimed is described in sufficient detail as to clearly show possession. However, there are more stringent requirements for descriptions of chemical species: a written description of an invention involving a chemical species "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to "distinguish it from other materials" (*In re Smythe*, 480 F2d 1376, 1383, 178 USPQ (BNA) 279, 284-85 (CCPA 1973)). Thus, possession of chemical species must be defined specifically, whereas possession of mechanical devices, for example, may be described with less detail.

In re Moore looked at *enablement* of a genus of chemical species: "The relevant inquiry may be summed up as being whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by

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the claims" (Judge Baldwin). It was determined in that case that the Applicants were actually claiming a mixture of compounds, and that they were enabled for the mixture. Written Description was not evaluated outright in that case, but of course the inventors must have been in possession of the claimed invention before it could be patented. It could not be determined by the examiner how Applicants intend to relate *In re Moore* to the facts of the instant Application.

To fulfill the written description requirement, a patent specification must describe an invention in sufficient detail such that one skilled in the art could clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 U.S.P.Q.2d at 1966. However, Applicants have not described or shown possession of all species of polypeptides *that are functionally equivalent to SEQ ID NO: 16*. Nor have Applicants described a representative number of species that could be considered a genus of PTH2 compounds that function in the same way (e.g., that stimulate the PTH2 receptor).

As discussed in the previous Office Action (14 May 2004) even a very skilled artisan could not envision the detailed chemical structure of all or a significant number of encompassed PTH2 compounds, and therefore, would not know how to use them. Adequate written description requires more than a mere statement that it is part of the invention and reference to a

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potential method of making. The claimed product itself is required. Recitation of the phrases "human PTHrP analogue" (Amended claims, 15 November 2004), and "where said analogue is a selective PTH2 receptor agonist" are not adequate to describe the claimed PTHrP analogue, since there was no reduction to practice to support the qualifying phrases in the claims. Applicants neither made nor tested variant PTHrP analogues, and as recited in the current Written Description Guidelines, Applicants must have invented the subject matter that is claimed and must be in "possession" of the claimed genus (Federal Register, 2001, Vol. 66, No. 4, pages 1099-1111, esp. page 1104, 3rd column).

Claim Rejections- Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7, 9-15 and 23-29 are rejected under the judicially created doctrine of double patenting over claims 1-23 of U. S. Patent No. 5,723,577 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claimed analogues of the instant Application are similar in structure to the

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claimed peptides and peptide analogues of Patent 5,723,577. The claimed analogues of Patent 5,723,577 are similar to the PTH analogues of the instant Application and would therefore possess the same inherent characteristics such as PTH2 binding affinity and efficacy (K_d and EC_{50} , respectively; see Table I of Patent 5,723,577).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 1-3, 7, 9-15 and 23-29 are rejected under the judicially created doctrine of double patenting over Claims 1-16 of U. S. Patent No. 5,717,062. The instant claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claimed analogues of the instant Application are similar in structure to the claimed peptides and peptide analogues of Patent 5,717,062. The claimed analogues of Patent 5,717,062 are similar to the PTH analogues of the instant Application and would therefore possess the same inherent characteristics, such as PTH2 binding affinity and efficacy.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim 1-3, 7, 9-15 and 23-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,995,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent 5,995,574 anticipates the instant claims. The claimed analogues of the instant Application are similar in structure to the claimed peptides and peptide analogues of Patent 5,995,574. The claimed analogues of Patent 5,995,574 are similar to the PTH analogues of the instant Application and would therefore possess the same inherent characteristics, such as PTH2 binding affinity and efficacy.

Claim Rejections- 35 USC § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 9-15 and 23-29 are rejected under 35 U.S.C. 102(b) as being unpatentable over Gardella, et al, (1996, J. Biol. Chem., 271(33): 19888-19893). Gardella, et al disclose human PTH analogues that are selective for the PTH2 receptor (see Table I and Figure 2B). They also make and test PTH analogues in which each residue is substituted or deleted (see in particular Figures 4-7). This reference meets the limitations of Claim 1-3, 7, 9-15 and 23-29 of "human PTH [] analogue" and PTH analogues comprising hPTH (1-31)-NH₂. Because of the

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similarity between the peptides disclosed in Gardella, et al and the instant Application, the peptides disclosed in the reference will have the same inherent binding properties at the PTH2 receptor as those of the instant Application.

Claims 1-3, 7 and 9 are rejected under 35 U.S.C. 102(b) as being unpatentable over Neugebauer and Willick, (1993, Peptides 1992, C.H. Schneider and A.N. Eberle (eds), ESCOM Science Publishers). Neugebauer and Willick make and disclose PTH analogues comprising hPTH (20-34). Because of the similarity between the peptides disclosed in Neugebauer and Willick and the instant Application, the peptides disclosed in the reference will have the same inherent binding properties at the PTH2 receptor as those of the instant Application.

Claims 1-3, 7 and 9 are rejected under 35 U.S.C. 102(b) as being unpatentable over Willick, et al, 1996 (U.S. Patent 5,556,940). Willick, et al disclose human PTH analogues that comprise hPTH (1-31)-NH₂, and they recite and use analogues from hPTH (1-28)-NH₂ to hPTH (1-31)-NH₂, and all sequences from [Leu²⁷]-hPTH-(1-28)-NH₂ to [Leu²⁷]-hPTH-(1-33)-NH₂. This reference meets the limitations of Claim 1-7 and 9 of "human PTH [] analogue" and PTH analogues comprising hPTH (1-31)-NH₂. Because of the similarity between the peptides disclosed in Patent 5,556,940 and the instant Application, the peptides disclosed in the patent will have the same inherent binding properties at the PTH2 receptor as those of the instant Application.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being unpatentable over Chorev, et al, (1990, Biochemistry, 29: 1580-1586). Chorev, et al, the teach PTH analogues of Formula I

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of the instant Application. That group modified or substituted most residues in the peptide and measured binding of the resultant peptides to the PTH receptor (see Tables I and II). This reference meets the limitations of Claims 1-3 and 7 of hPTH analogues. The disclosed peptides from Chorev, et al are the same as the claimed analogues and would therefore inherently interact in a similar way with the PTH2 receptor.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being unpatentable over Rosenblatt, et al, 1991 (US Patent 5,001,223). Rosenblatt et al. teach PTH analogues, and claim and use [D-Phe⁷, Tyr³⁴]hPTH7-34NH₂. This reference meets the limitations of Claims 1-3 and parts of dependent claims of hPTH analogues. The disclosed peptides from Rosenblatt, et al are the same as the claimed analogues and would therefore inherently interact in a similar way with the PTH2 receptor.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 7, 9-15 and 23-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,717,062. See the obviousness-type double patenting rejection above.

The applied reference has two inventors in common with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

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inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-3, 7, 9-15 and 23-29 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,955,574. See the obviousness-type double patenting rejection above.

The applied reference has one inventor in common with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections- 35 USC § 112, second paragraph – Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 9, 10, 12, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7, 9, 10, 12, 13 and 14 list R¹ and R² substitutions as a Markush group (see the section defining A³⁸), but then use "or" before listing the final species in the list:

"R¹ and R² are each independently selected from the

group consisting of H, (C₁-C₃₀)alkyl, (C₁-C₃₀)alkenyl,

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phenyl- (C₁-C₃₀)alkyl, naphthyl (C₁-C₃₀)alkyl,
hydroxy (C₁-C₃₀)alkyl, hydroxy(C₁-C₃₀)alkenyl, hydroxy-
phenyl(C₁-C₃₀)alkyl or hydroxy-naphthyl(C₁-C₃₀)alkyl"

Claims 7, 9, 10, 12, 13 and 14 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite, because there is no antecedent basis for use of the word "compound" near the end of each listed claim:

"provided that the **compound** is not PTH(1-34)R³ (SEQ ID NO:4),
PTH(1-35)R³ (SEQ ID NO: 5), PTH(1-36)R³ (SEQ ID NO:6), PTH(1-37)R³ (SEQ
ID NO:7) or PTH(1-38)R³ (SEQ ID NO:8)."

Additional References:

Dong, Z.X., 1999, U.S. Patent 5,969,095.

Holick, M.F., 1996, U.S. Patent 5,527,772.

Gardella, T.J., 2002, U.S. Patent 6,362,163.

Yamamoto, et al, 1997, Endocrinology, 138(5): 2066-2072.

Usdin, et al, 1995, J. Biol. Chem., 270(26): 15455-15458.

Duvos, et al, 1993, U.S. Patent 5,783,558.

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Conclusion

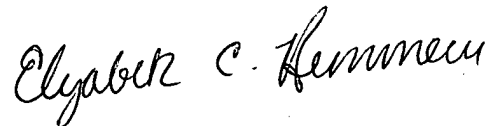
No claims are allowed.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
29 March 2005



ELIZABETH KEMMERER
PRIMARY EXAMINER